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<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/002,038	LEMUS ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	LaToya C. Younger	1743	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**  
 All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 11-23-05.
2. ☒ The allowed claim(s) is/are 1-3, 7-14 and 17-21.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
  1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

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|---|---|
| <ol style="list-style-type: none"> <li>1. <input type="checkbox"/> Notice of References Cited (PTO-892)</li> <li>2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br/>Paper No./Mail Date _____</li> <li>4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br/>of Biological Material</li> </ol> | <ol style="list-style-type: none"> <li>5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)</li> <li>6. <input type="checkbox"/> Interview Summary (PTO-413),<br/>Paper No./Mail Date _____.</li> <li>7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment</li> <li>8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance</li> <li>9. <input type="checkbox"/> Other _____.</li> </ol> |
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### EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Attorney Andrew Farmer on February 6, 2006.

The application has been amended as follows:

- Amend claim 1 as follows:
  1. (Amended) A sterilization process challenge device comprising:
    - a sterilization indicator contained within a container; and
    - a variable diffusion restriction into said container,
    - wherein the variable diffusion restriction comprises a diffusion path into said container,
    - and the diffusion path comprises an adjustable covering for said path to block or unblock a
    - portion of said diffusion path and wherein the container comprises a first member and a
    - second member disposed in telescoping relation with a plurality of openings disposed on
    - the first member and the second member forming the adjustable covering.
- Cancel claims 4, 5 and 6.
- In claim 7, delete the phrase "claim 4" and insert therefor -- claim 1 --.
- In claim 10, delete the phrase "claim 4" and insert therefor -- claim 1 --.
- In claim 11, delete the phrase "claim 4" and insert therefor -- claim 1 --.
- In claim 13, delete the phrase "claim 4" and insert therefor -- claim 1 --.
- Amend claim 14 as follows:

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14. (Amended) A method for assessing the sterilization efficacy of a sterilization process comprising the steps of:

Placing a sterilization process challenge device in proximity to a device to be sterilized during the sterilization process, the sterilization process challenge device comprising a container, a sterilization indicator within the container, an opening into said container and an adjustable diffusion restriction at said opening;

assessing a feature of a load of one or more device to be sterilized in said sterilization process;

adjusting the amount of diffusion restriction provided by said diffusion restriction based upon said feature of said load; and

indicating the sterilization efficacy with the indicator,

wherein the step of adjusting the amount of diffusion restriction comprises adjusting an area of the opening into the container and wherein the area of opening into the container is adjusted by covering and uncovering the opening into the container.

- Cancel claims 15 and 16.
- In claim 17, delete the phrase "claim 16" and insert therefor - - claim 14 - -.

2. The following is an examiner's statement of reasons for allowance: The amendment to claim 1 requires that the variable diffusion restriction into the container be a diffusion path comprising an adjustable covering for blocking or unblocking a portion of said diffusion path and further requires that the container have first and second members disposed in telescoping relation with a plurality of openings disposed on the first member, while the second member forms the adjustable covering. Hendricks et al teach a sterilization indicator device comprising a container holding a sterilization indicator and a foam

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plug for regulating the amount of sterilant entering the container. Hendricks et al fail to teach or reasonable suggest a container having first and second members disposed in telescoping relation with openings on a first member and the second member forming an adjustable covering. With respect to claim 14, Hendricks et al fail to teach or reasonably suggest adjusting the amount of diffusion restriction by adjusting an area of the opening of the container via covering or uncovering the opening to the container.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya C. Younger whose telephone number is 571-272-1256. The examiner can normally be reached on Monday-Thursday 10:30 a.m. - 7:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Jill Warden  
Supervisory Patent Examiner  
Technology Center 1700